WHAT IS CLAIMED IS:

1. A substantially non-irritating pharmaceutical formulation for topical and/or transdermal administration of the agent 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine, which formulation comprises:

(a) 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine in an amount of about 0.5 percent to about 9 percent by weight based on the total weight of said formulation; and

(b) a pharmaceutically acceptable vehicle for said 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine, which vehicle comprises a fatty acid selected from the group consisting of isostearic acid, oleic acid and a mixture thereof in a total amount of about 3 percent to about 45 percent by weight based on the total weight of said formulation, said formulation being further characterized in that, when tested according to the hairless mouse skin model the formulation provides a penetration of the agent of at least about 10 percent of the total amount of the agent contained in the formulation in 24 hours.

2. A formulation according to Claim 1 wherein said fatty acid is isostearic acid.

3. A formulation according to Claim 1 wherein said fatty acid is oleic acid.

4. A formulation according to Claim 1 wherein said fatty acid is a mixture of isostearic acid and oleic acid.

5. A formulation according to Claim 1 wherein said 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine is present in an amount of about 1 percent to about 7 percent by weight based on the total weight of said formulation.

6. A formulation according to Claim 1 in the form of a cream, comprising an oil phase and a water phase in admixture, said oil phase comprising:

(a) 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine;

(b) said fatty acid or mixture of said fatty acids;

(c) one or more emollients present in a total amount of about 5 percent to about 30 percent by weight based on the total weight of said formulation;

(d) one or more emulsifiers selected from the group consisting of a nonionic surface active agent and a trivalent cationic emulsifier and present in a total amount of about 2 percent to about 14 percent by weight based on the total weight of said formulation; and

(e) one or more thickeners present in a total amount of about 3 percent to about 12 percent by weight based on the total weight of said formulation; and

said water phase comprising water in an amount of about 45 percent to about 85 percent by weight based on the total weight of said formulation.

7. A formulation according to Claim 6 wherein said 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine is present in an amount of about 1 percent to about 5 percent by weight based on the total weight of said formulation.

8. A formulation according to Claim 6 wherein said fatty acid is isostearic acid and is present in an amount of about 5 percent to about 25 percent by weight based on the total weight of said formulation.

9. A formulation according to Claim 8, comprising about 1 percent of said 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine, about 10 percent of said isostearic acid, about 2 percent benzyl alcohol, about 2.2 percent cetyl alcohol, about 3.1 percent stearyl alcohol, about 2.55 percent polysorbate 60, about 0.45 percent sorbitan monostearate, about 2 percent glycerin, about 0.2 percent methylparaben, about 0.02 percent propylparaben and about 76.48 percent purified water, all percentages being based on the total weight of said formulation.

10. A formulation according to Claim 8, comprising about 1 percent of said 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine, about 10 percent of said isostearic acid, about 6 percent cetearyl alcohol, about 2.55 percent polysorbate 60, about 0.45 percent sorbitan monostearate, about 2 percent glycerin, about 0.2 percent methylparaben, about 0.02 percent propylparaben and about 77.78 percent purified water, all percentages being based on the total weight of said formulation.

11. A formulation according to Claim 8, comprising about 1 percent of said 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine, about 10 percent of said isostearic acid, about 2 percent benzyl alcohol, about 1.7 percent cetyl alcohol, about 2.3 percent stearyl alcohol, about 2.55 percent polysorbate 60, about 0.45 percent sorbitan monostearate, about 2 percent glycerin, about 0.2 percent methylparaben, about 0.02 percent propylparaben and about 77.78 percent purified water, all percentages being based on the total weight of said formulation.

12. A formulation according to Claim 8, comprising about 5 percent of said 1-isobutyl-1H-imidazo-[4,5-c]quinolin-4-amine, about 25 percent of said isostearic acid, about 2 percent benzyl alcohol, about 2.2 percent cetyl alcohol, about 3.1 percent stearyl alcohol, about 3 percent petrolatum, about 3.4 percent polysorbate 60, about 0.6 percent sorbitan monostearate, about 2 percent glycerin, about 0.2 percent methylparaben, about 0.02 percent propylparaben and about 53.48 percent purified water, all percentages being based on the total weight of said formulation.

13. A formulation according to Claim 8, comprising about 1 percent of said 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine, about 5 percent of said isostearic acid, about 15 percent petrolatum, about 12.8 percent light mineral oil, about 8 percent aluminum stearate, about 4 percent cetyl alcohol, about 3 percent polyglyceryl-4 oleate, about 1 percent acetylated lanolin, about 0.063 percent propylparaben, about 1 percent Veegum K, about 0.12 percent methylparaben and about 49.02 percent purified water, all percentages being based on the total weight of said formulation.

14. A formulation according to Claim 1 in the form of an ointment comprising:

(a) 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine in an amount of about 0.5 percent to about 5 percent by weight based on the total weight of said formulation;

(b) a fatty acid selected from the group consisting of isostearic acid, oleic acid and a mixture thereof in a total amount of about 3 percent to about 25 percent by weight based on the total weight of said formulation; and

(c) a pharmaceutically acceptable ointment base in an amount of about 60 percent to about 95 percent by weight based on the total weight of said formulation.

15. A formulation according to Claim 14 wherein said fatty acid is isostearic acid.

16. A formulation according to Claim 1, wherein said pharmaceutically acceptable vehicle further comprises a pressure-sensitive acrylic adhesive copolymer comprising, as a major constituent, a hydrophobic monomeric acrylic or methacrylic acid ester of an alkyl alcohol, the alkyl alcohol containing 4 to 10 carbon atoms, said copolymer being present in an amount of about 55 percent to about 85 percent by weight based on the total weight of said formulation.

17. A formulation according to Claim 16 in the form of a pressure-sensitive adhesive-coated sheet material comprising:

(a) a flexible backing; and

(b) a pressure-sensitive adhesive coating adhered to one surface of said backing and comprising a mixture of:

i) an acrylic copolymer comprising, as a major constituent, a hydrophobic monomeric acrylic or methacrylic acid ester of an alkyl alcohol, the alkyl alcohol containing 4 to 10 carbon atoms;

ii) 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine in an amount of about 0.5 percent to about 9 percent by weight based on the total weight of said adhesive coating; and

iii) a fatty acid selected from the group consisting of isostearic acid, oleic acid or a mixture thereof, said fatty acid being present in a total amount of about 10 percent to about 40 percent by weight based on the total weight of said adhesive coating.

18. A formulation according to Claim 17, wherein said acrylic copolymer comprises A and B Monomers as follows:

A is a hydrophobic monomeric acrylic or methacrylic acid ester of an alkyl alcohol, the alkyl alcohol containing 4 to 10 carbon atoms, said A monomer being present in an amount by weight of about 80 percent to about 98 percent based on the total weight of all monomers in said copolymer; and

B is a reinforcing monomer selected from the group consisting of acrylic acid, methacrylic acid, an alkyl acrylate or methacrylate containing 1 to 3 carbon atoms in the alkyl group, acrylamide, methacrylamide, a lower alkyl-substituted acrylamide, diacetone acrylamide, N-vinyl-2-pyrrolidone, a vinyl ether, a substituted ethylene and a vinyl ester, said B monomer being present in an amount of about 2 percent to about 20 percent based on the total weight of all monomers in said copolymer.

19. A formulation according to Claim 18, wherein said adhesive copolymer comprises about 2 percent to about 10 percent by weight of acrylamide and about 90 percent to about 98 percent by weight of isooctyl acrylate, based on the total weight of all monomers in said copolymer.

20. A formulation according to Claim 17, wherein said 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine is present in an amount of about 3 percent to about 7 percent by weight based on the total weight of said adhesive coating.

21. A formulation according to Claim 17, wherein said adhesive coating further comprises a skin penetration enhancer selected from the group consisting of isopropyl myristate, diisopropyl adipate, ethyl oleate, glyceryl monolaurate, ethyl oleate in combination with glyceryl monolaurate, ethyl oleate in combination with N,N-dimethyldodecylamine-N-oxide, glyceryl monolaurate in combination with N,N-dimethyldodecylamine-N-oxide, and ethyl oleate in combination with both glyceryl monolaurate and N,N-dimethyldodecylamine-N-oxide, said skin penetration enhancer being present in an amount of about 3 percent to about 25 percent by weight based on the total weight of said adhesive coating.

22. A formulation according to Claim 21, wherein said skin penetration enhancer(s) is present in a total amount of about 3 percent to about 10 percent by weight based on the total weight of said adhesive coating.

23. A formulation according to Claim 21, wherein said skin penetration enhancer comprises ethyl oleate in an amount of about 5 percent to about 8 percent by weight based on the total weight of said adhesive coating, glyceryl monolaurate in an amount between about 1 percent to about 2 percent by weight based on the total weight of said adhesive coating and N,N-dimethyldodecylamine-N-oxide in an amount of about 1 percent to about 3 percent by weight based on the total weight of said adhesive coating.

24. A pressure-sensitive adhesive-coated sheet material comprising:

a) a flexible backing; and

b) a pressure-sensitive adhesive coating adhered to one surface of said flexible backing and comprising a mixture of:

i) a pressure-sensitive acrylic adhesive copolymer comprising about 93 percent by weight, based on the total weight of the copolymer, of isooctyl acrylate and about 7 percent by weight, based on the total weight of the copolymer, of acrylamide;

ii) the compound 1-isobutyl-1H-imidazo[4,5-c]-quinolin-4-amine in an amount by weight of about 5 percent based on the weight of said adhesive coating;

iii) isostearic acid in an amount by weight of about 10 percent based on the weight of said adhesive coating;

iv) oleic acid in an amount by weight of about 20 percent based on the weight of said adhesive coating; and

v) as a skin penetration enhancing combination (1) ethyl oleate in an amount by weight of about 5 percent based on the weight of said adhesive coating (2) glyceryl monolaurate in an amount by weight of about 1.5 percent based on the weight of said adhesive coating; and (3) N,N-dimethyldodecylamine-N-oxide in an amount by weight of about 1 percent based on the weight of said adhesive coating.

25. A formulation according to Claim 1, wherein said pharmaceutically acceptable vehicle further comprises a pressure-sensitive acrylic adhesive copolymer comprising:

about 60 to about 80 percent by weight of hydrophobic monomeric acrylic or methacrylic acid ester of an alkyl alcohol, the alkyl alcohol containing 4 to about 10 carbon atoms, based on the total weight of all monomers in the copolymer;

about 4 to about 9 percent by weight based on the total weight of all monomers in the copolymer of a reinforcing monomer selected from the group consisting of acrylic acid, methacrylic acid, an alkyl acrylate or methacrylate containing 1 to 3 carbon atoms in the alkyl group, acrylamide, methacrylamide, a lower alkyl-substituted acrylamide, diacetone acrylamide and N-vinyl-2-pyrrolidone; and

about 15 to about 35 percent by weight of vinyl acetate based on the total weight of all monomers in the copolymer,

said copolymer being present in an amount of about 55 percent to about 85 percent by weight based on the total weight of said formulation.

26. A formulation according to Claim 1, wherein said pharmaceutically acceptable vehicle further comprises a pressure-sensitive acrylic adhesive copolymer comprising:

about 70 to about 80 percent by weight of hydrophobic monomeric acrylic or methacrylic acid ester of an alkyl alcohol, the alkyl alcohol containing 4 to about 10 carbon atoms, based on the total weight of all monomers in the copolymer;

about 4 to about 9 percent by weight based on the total weight of all monomers in the copolymer of a reinforcing monomer selected from the group consisting of acrylic acid, methacrylic acid, an alkyl acrylate or methacrylate containing 1 to 3 carbon atoms in the alkyl group, acrylamide, methacrylamide, a lower alkyl-substituted acrylamide, diacetone acrylamide and N-vinyl-2-pyrrolidone; and

about 15 to about 25 percent by weight of vinyl acetate based on the total weight of all monomers in the copolymer,

said copolymer being present in an amount of about 55 percent to about 85 percent by weight based on the total weight of said formulation.

27. A formulation according to Claim 25 in the form of a pressure-sensitive adhesive-coated sheet material comprising:

(a) a flexible backing; and

(b) a pressure-sensitive adhesive coating adhered to one surface of said backing and comprising a mixture of:

i) an acrylic copolymer comprising:

about 60 to about 80 percent by weight of hydrophobic monomeric acrylic or methacrylic acid ester of an alkyl alcohol, the alkyl alcohol containing 4 to about 10 carbon atoms, based on the total weight of all monomers in the copolymer;

about 4 to about 9 percent by weight based on the weight of all monomers in the copolymer of a reinforcing monomer selected from the group consisting of acrylic acid, methacrylic acid, an alkyl acrylate or methacrylate containing 1 to 3 carbon atoms in the alkyl group, acrylamide, methacrylamide, a lower alkyl-substituted acrylamide, diacetone acrylamide and N-vinyl-2-pyrrolidone; and

about 15 to about 35 percent by weight of vinyl acetate based on the total weight of all monomers in the copolymer;

ii) 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine in an amount of about 0.5 percent to about 9 percent by weight based on the total weight of said adhesive coating; and

iii) a fatty acid selected from the group consisting of isostearic acid, oleic acid or a mixture thereof, said fatty acid being present in a total amount of about 10 percent to about 40 percent by weight based on the total weight of said adhesive coating.

28. A formulation according to Claim 27, wherein said 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine is present in an amount of about 3 percent to about 7 percent by weight based on the total weight of said adhesive coating.

29. A formulation according to Claim 27, wherein said adhesive coating further comprises a skin penetration enhancer selected from the group consisting of isopropyl myristate, diisopropyl adipate, ethyl oleate, glyceryl monolaurate, ethyl oleate in combination with glyceryl monolaurate, ethyl oleate in combination with N,N-dimethyldodecylamine-N-oxide, glyceryl monolaurate in combination with N,N-dimethyldodecylamine-N-oxide, and ethyl oleate in combination with both glyceryl monolaurate and N,N-dimethyldodecylamine-N-oxide, said skin penetration enhancer being present in an amount of about 3 percent to about 25 percent by weight based on the total weight of said adhesive coating.

30. A formulation according to Claim 29, wherein said skin penetration enhancer(s) is present in a total amount of about 3 percent to about 10 percent by weight based on the total weight of said adhesive coating.

31. A formulation according to Claim 29, wherein said skin penetration enhancer comprises ethyl oleate in an amount of about 5 percent to about 8 percent by weight based on the total weight of said adhesive coating, glyceryl monolaurate in an amount between about 1 percent to about 2 percent by weight based on the total weight of said adhesive coating and N,N-dimethyldodecylamine-N-oxide in an amount of about 1 percent to about 3 percent by weight based on the total weight of said adhesive coating.

32. A method of topical and/or transdermal administration of 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine for treating a viral disease in a mammal, which method comprises

(1) placing a formulation according to Claim 1 on the skin of a mammal; and

(2) allowing said formulation to remain in contact with the skin for a sufficient time to permit an effective amount of the 1-isobutyl-1H-imidazo[4,5-c]-quinolin-4-amine to penetrate the skin to achieve the antiviral effect.

33. A method of topical and/or transdermal administration of 1-isobutyl-1H-imidazo[4,5-c]-quinolin-4-amine to induce interferon biosynthesis in a mammal, which method comprises

(1) placing a formulation according to Claim 1 on the skin of a mammal; and

(2) allowing said formulation to remain in contact with the skin for a sufficient time to permit an effective amount of 1-isobutyl-1H-imidazo[4,5-c]-quinolin-4-amine to penetrate the skin to induce interferon biosynthesis.

Add C1

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